

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

CHERI LEONARD,
Plaintiff,

v.

CVS PHARMACY, INC., et al.,
Defendants.

Case No. [5:24-cv-06280-EJD](#)

**ORDER GRANTING MOTION TO
DISMISS WITH LEAVE TO AMEND**

Re: Dkt. No. 47

Plaintiff Cheri Leonard (“Plaintiff”), on behalf of herself and a class of similarly situated individuals, brings various California consumer protection claims against Defendants CVS Pharmacy, Inc. (“CVS”), Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals LLC (collectively, “Amneal”) (all together, “Defendants”) arising from the alleged presence of benzene in Defendants’ products. First. Am. Compl. (“FAC”), ECF No. 33. Before the Court is Defendants’ motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Mot., ECF No. 47. This motion is fully briefed. Opp’n, ECF No. 59; Reply, ECF No. 60.

After careful review of the relevant documents, the Court finds this motion suitable for decision without oral argument pursuant to Local Rule 7-1(b). For the reasons explained below, the Court **GRANTS** Defendants’ motion to dismiss with leave to amend.

I. BACKGROUND

Plaintiff alleges that Amneal manufactured, and CVS sold, guaifenesin-containing

1 medications (“Products”)¹ that included a carbomer manufactured with benzene. FAC ¶¶ 1, 2.

2 The Products are marketed as a generic formulation of the brand-name Mucinex. *Id.* ¶ 2.
3 The Products and Mucinex both list carbomer as an inactive ingredient. *Id.* ¶ 4. Carbomer is
4 widely used in drugs as a gelling or binding agent and is sometimes manufactured using benzene.
5 *Id.* ¶ 6, 48. Benzene is a known carcinogenic that has been linked to cancer and other medical
6 conditions in studies cited by Plaintiff. *Id.* ¶¶ 5–8. Although some carbomers—such as those used
7 in Mucinex—are not manufactured using benzenes, it is generally cheaper to manufacture
8 carbomers with benzene. *Id.* ¶ 6. Plaintiff alleges that Amneal used a carbomer manufactured
9 with benzene in the Products to save costs.

10 The Products are considered time-released over-the-counter (“OTC”) drugs, which require
11 FDA approval. Mot. 3. To obtain such approval, Amneal submitted an Abbreviated New Drug
12 Application (“ANDA”) to the FDA. Req. for J. Notice (“RJN”), Exs. 2, 3, ECF Nos. 49, 61.²
13 Under FDA regulations, ANDAs must disclose each component of the drug and its specifications,
14 including the identification and characterization of inactive ingredients, along with data
15 demonstrating that the ingredients do not affect the drug’s safety or efficacy. 21 C.F.R. §§
16 314.50(d)(1)(ii)(a), 314.94(a)(9)(i) (incorporating § 314.50(d)(1) for ANDAs), 314.94(a)(9)(ii).
17 The FDA reviewed and approved Amneal’s guaifenesin ANDAs in 2018. RJN, Exs. 2, 3. By
18 approving the ANDAs, the FDA authorized the Products’ labels and the use of the carbomer listed
19 as an inactive ingredient, which is the carbomer manufactured with benzene. *Id.*

20
21
22 ¹ Plaintiff lists five Products in the FAC: (1) CVS-branded Maximum Strength Mucus Extended
23 Release, Guaifenesin Extended-Release Tablets, 1200 mg; (2) CVS-branded Mucus Extended
24 Release, Guaifenesin Extended-Release Tablets, 600 mg; (3) CVS Health 12HR Maximum
Strength Mucus DM Extended Release Tablets, 1200mg/60mg; (4) CVS Health 12HR Mucus DM
Extended Release Cough Tablets, 600mg/30mg; and (5) CVS Health 12HR Maximum Strength
Cough and Congestion Relief Extended Release Tablets. FAC ¶ 2.

25 ² Pursuant to Federal Rule of Evidence 201, the Court **GRANTS** Defendant’s unopposed request
26 for judicial notice. Req. for J. Notice (“RJN”), ECF Nos. 49, 61. The Court takes judicial notice
27 of documents including: FDA National Drug Code database file; FDA approval pages for
Amneal’s ANDAs; National Library of Medicine (“NIH”) DailyMed webpages for the Products;
FDA guidance and articles; and USP updates and monographs. *Id.* The Court finds these
documents are either incorporated to or relied upon in the complaint, or capable of being
accurately and readily determined from sources whose accuracy cannot be questioned.

Specifications for inactive ingredients like carbomers are established in monographs published by the United States Pharmacopeia (“USP”). FAC ¶ 39 n.17–18. The monographs for carbomers have recently undergone changes. In December 2023, the FDA issued guidance concerning five USP carbomer monographs that allowed benzene levels of “up to 5,000ppm.” RJN, Ex. 6 at 3, Ex. 7. At the FDA’s request, USP issued a Notice of Intent to omit these monographs by August 1, 2025. RJN, Ex. 6 at 1 n.3. USP subsequently changed this target date to August 1, 2026. RJN, Ex. 8. Manufacturers using the affected carbomers will be required to reformulate their products once the monographs are removed in August 2026. *Id.* at 4. The FDA guidance also recommends that manufacturers test their products for benzene contamination and refrain from releasing any batch containing benzene levels exceeding 2 ppm. *Id.* at 3–4. In response, Amneal publicly announced its intent to submit reformulated versions of the Products for FDA approval. RJN, Ex. 6 at 1 n.3.

Plaintiff alleges that she purchased CVS-branded Maximum Strength Mucus Extended Release, Guaifenesin Extended-Release Tablets, 1200 mg from a CVS retail location in Felton, California in July 2024. FAC ¶ 14. This product, along with the other Products listed in the FAC, are allegedly manufactured by Defendant Amneal and contain benzene. *Id.* ¶¶ 1, 2. Plaintiff filed this case on September 5, 2024, bringing five claims arising out of the presence of benzene in the Products: (1) breach of implied warranty of merchantability, (2) unjust enrichment, (3) fraud, (4) violation of California’s consumer legal remedies act, Cal. Civ. Code § 1750, et seq., and (5) violation of California’s unfair competition law, Cal. Bus. & Prof. Code § 17200, et seq. Compl., ECF No. 1. Plaintiff claims that had Defendants disclosed the presence of benzene, she would not have purchased the Product or would have paid less for it, and she seeks compensatory and punitive damages, restitution, and attorneys’ fees and costs. *See* FAC.

II. LEGAL STANDARD

A. Rule 12(b)(1)

A district court must dismiss an action if it lacks jurisdiction over the subject matter of the suit. Fed. R. Civ. Pro. 12(b)(1). “The plaintiff, as the party invoking federal jurisdiction, bears the

burden of establishing” the elements of standing: injury in fact, causation, and redressability. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) *as revised* (May 24, 2016). Once a defendant moves to dismiss for lack of subject matter jurisdiction, the plaintiff has the burden of establishing the court’s jurisdiction. *Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1122 (9th Cir. 2010).

B. Rule 12(b)(6)

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A plaintiff must “plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged,” which requires “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* The court must “accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party.” *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). However, courts “are not bound to accept as true a legal conclusion couched as a factual allegation.” *Ashcroft*, 556 U.S. at 678.

If the court concludes that a Rule 12(b)(6) motion should be granted, the “court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts.” *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (quotation omitted).

III. DISCUSSION

The Court will address in turn Defendants’ arguments regarding personal jurisdiction over Amneal, Article III standing, and preemption.

A. Personal Jurisdiction

Amneal first argues that the Court does not have personal jurisdiction over either company because they are incorporated in Delaware with principal places of business in New Jersey and New York. The exercise of personal jurisdiction over a nonresident defendant must be authorized

under the state’s long-arm statute and must satisfy the due process clause of the United States Constitution. *Perez v. United States*, 103 F. Supp. 3d 1180, 1197 (S.D. Cal. 2015). California’s long-arm statute permits the exercise of personal jurisdiction “on any basis not inconsistent with the Constitution of this state or of the United States.” Cal. Civ. Proc. Code § 410.10. Under the due process analysis, a defendant may be subject to either general or specific personal jurisdiction. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984). At issue here is specific jurisdiction, which requires courts to apply a three-part test: (1) the nonresident defendant must do some act or consummate some transaction with the forum or perform some act by which he purposefully avails himself of the privilege of conducting activities in the forum, thereby invoking the benefits and protections of its laws; (2) the claim must be one which arises out of or results from the defendant’s forum-related activities; and (3) exercise of jurisdiction must be reasonable. *Schwarzenegger v. Fred Martin Motor Co.*, 374 F.3d 797, 802 (9th Cir. 2004). Plaintiffs bear the burden to satisfy the first two elements, then the burden shifts to the defendants to “present a compelling case” that the exercise of jurisdiction would be unreasonable. *Goodwin Procter, LLP v. Gibson*, No. 12-CV-02167 NC, 2012 WL 12921028, at *4 (N.D. Cal. July 23, 2012) (citing *Schwarzenegger*, 374 F.3d at 802).

Amneal challenges only the first requirement: purposeful availment. Purposeful availment requires, in relevant part, that a defendant expressly aims its conduct at the forum state.³ *Ayla, LLC v. Ayla Skin Pty. Ltd.*, 11 F.4th 972, 980 (9th Cir. 2021). Amneal argues that Plaintiff failed to show Amneal purposefully availed itself of California’s jurisdiction because it did not engage in conduct expressly aimed at California. The Court disagrees.

Amneal does not sell the Products in California or any other state. Instead, Amneal sells to a distributor in New York, who then repackages, relabels, and resells the Products to CVS. The distributor decides where to sell the Products, not Amneal. However, the distributor maintains facilities in only four states, of which California is one. These circumstances are analogous to

³ Amneal does not challenge the remaining two elements—“an intentional act” and “causing harm that the defendant knows is likely to be suffered in the forum state.” *Ayla*, 11 F.4th at 980.

Digitech Image Techs., LLC v. Mamiya Digital Imaging Co., LTD., et al., No. 8:12-CV-1675-ODW, 2013 WL 1415121, at *4 (C.D. Cal., Apr. 8, 2013), where the court found that the defendant was “fully aware that its allegedly infringing products will and do reach California through the stream of commerce” because the defendant sold products to a U.S. distributor from New York that listed seven California retail locations on its website. *See also L.W. v. Audi AG*, 108 Cal. App. 5th 95, 114 (2025), *reh’g denied* (Feb. 6, 2025), *review denied* (Apr. 23, 2025) (noting that “the involvement of [the defendant] itself within the forum state is not necessarily required” and finding personal jurisdiction established where the defendant used a distributor specifically to distribute cars to dealerships throughout California). Similarly here, Amneal should have expected its products would reach California given the distributor’s limited presence in only four states. *See World-Wide Volkswagen Corp. v. Woodson*, 100 S. Ct. 559, 567 (1980) (“The forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State.”). The Court finds this sufficient to establish conduct expressly aimed at California.

Amneal highlights that it does not advertise or market the Products in California, or any other state, and does not engage in any e-commerce websites where consumers can purchase the Products. But a defendant can still direct its conduct toward a forum state without personally selling products or advertising the products to be sold there. *See World-Wide Volkswagen Corp.*, 444 U.S. at 297–98. Amneal also argues that, under *Bombardier Recreational Prods., Inc. v. Dow Chem. Canada ULC*, 216 Cal. App. 4th 591, 603 (2013), the Court cannot assert personal jurisdiction over Amneal based solely on its foreseeing that the Products would end up in California. But in *Bombardier*, the only contact in California was the defendant’s “mere knowledge” that its client would use the defendant’s fuel tanks in a “personal watercraft that would be sold in California.” *Id.* at 604. The California Court of Appeal found this was insufficient to establish personal jurisdiction “without something more.” *Id.* Whereas here, Amneal sold products directly to a distributor with facilities in only four states, of which

California is one. This connection is far less attenuated than the facts in *Bombardier* and goes beyond the “mere knowledge” that a product will somehow make its way into California. *See id.*

Further, though insufficient on its own, the fact that Amneal is registered to do business in California with the California Secretary of State and maintains registered agents in California for service of process also supports finding personal jurisdiction. FAC ¶ 26; *see Bugarin v. All Nippon Airways Co.*, 513 F. Supp. 3d 1172, 1186 (N.D. Cal. 2021) (finding that the defendant being registered with the California Secretary of State and maintaining a registered agent for service of process in California supported finding personal jurisdiction); *Loomis v. Slendertone Distribution, Inc.*, 420 F. Supp. 3d 1046, 1070 (S.D. Cal. 2019) (same).

Accordingly, the Court finds that it has personal jurisdiction over Amneal.

B. Standing

Defendants next argue that Plaintiff lacks Article III standing. “The plaintiff has the burden of establishing the three elements of Article III standing: (1) he or she has suffered an injury in fact that is concrete and particularized, and actual or imminent; (2) the injury is fairly traceable to the challenged conduct; and (3) the injury is likely to be redressed by a favorable court decision.” *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1225 (9th Cir. 2008) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)). At the pleading stage, the plaintiff has the burden to establish standing by “clearly . . . allege facts demonstrating each element.” *Spokeo*, 578 U.S. at 338 (2016), *as revised* (May 24, 2016). Courts must assume the merits of a plaintiff’s claim when considering Article III standing. *Zeiger v. WellPet LLC*, 304 F. Supp. 3d 837, 843 (N.D. Cal. 2018).

Defendants argue that Plaintiff fails to plead the first element—a particularized injury—because she did not plead facts to show that the specific product she purchased contained benzine or that Amneal manufactured any of the Products. Again, the Court disagrees.

Plaintiff alleges that she “purchased CVS-branded Maximum Strength Mucus Extended Release, Guaifenesin Extended-Release Tablets, 1200 mg from a CVS retail location in Felton, California” in July 2024. FAC ¶ 14. This product, among the other Products, is allegedly an

“over-the-counter medication[] sold by CVS and manufactured by Amneal containing the inactive ingredient carbomer.” *Id.* ¶ 2; *id.* ¶ 14 (alleging that the label on the product “lists ‘carbomer’ as an inactive ingredient”). Plaintiff believes the product she purchased contained benzene and was manufactured by Amneal because “Amneal has admitted that finished doses of the Products contain benzene,” and Amneal is now changing its Products to comply with recent FDA requirements to remove benzene from its Products. *Id.* ¶ 9; *id.* ¶ 44.

Accepting these allegations as true, the Court finds these facts sufficiently establish a particularized injury. Though Plaintiff did not test the specific product she purchased for the presence of benzene, her allegation that “Amneal has admitted that finished doses of the Products contain benzene” is sufficient at this stage to establish both that the product Plaintiff purchased contained benzene, and it was manufactured by Amneal.⁴ *See Rodriguez v. Mondelez Glob. LLC*, 703 F. Supp. 3d 1191, 1205 (S.D. Cal. 2023), *reconsideration denied*, No. 23-CV-00057-DMS-AHG, 2024 WL 1361892 (S.D. Cal. Mar. 29, 2024) (“Plaintiffs need not allege that the specific Products they purchased had unsafe levels of lead and/or cadmium, but may simply aver facts from which this Court can make such reasonable inference. The FAC permits such a reasonable inference.”) (internal quotation marks and citation omitted); *Solis v. Coty, Inc.*, No. 22-CV-0400-BAS-NLS, 2023 WL 2394640, at *11 (S.D. Cal. Mar. 7, 2023) (“[T]his Court respectfully disagrees Solis must, as a matter of law, proffer a formulaic recitation that the specific unit of Product she purchased contains PFAS. Defendants do not cite to any Ninth Circuit decision that goes so far.”); *Grausz v. Hershey Co.*, 691 F. Supp. 3d 1178, 1188 (S.D. Cal. 2023) (“Hershey does not cite any Ninth Circuit decision which states Plaintiff must, as a matter of law, proffer a formulaic recitation that the specific unit of Product she purchased contains heavy metals, and the

⁴ Though Plaintiff also submitted evidence in her opposition to show the Products were manufactured by Amneal, this evidence is unnecessary at this stage. *Bowen v. Energizer Holdings, Inc.*, 118 F.4th 1134, 1149 n.13 (9th Cir. 2024) (“[The plaintiff] was not required to [put forth evidence] to withstand Defendants’ motion to dismiss.”). Notably, Defendants also admit that “[s]ome carbomers are manufactured using benzene and, as a result, may contain residual amounts of benzene in finished form,” and that “Amneal uses one such carbomer in its guaifenesin products.” Mot. 4.

1 Court finds none.”) (cleaned up).

2 Accordingly, the Court finds Plaintiff sufficiently pled standing.

3 **C. Preemption**

4 Finally, Defendants argue that Plaintiff’s claims are preempted by the Federal Drug and
5 Cosmetics Act (“FDCA”). On this point, the Court agrees.

6 Congress enacted the FDCA as a comprehensive federal scheme of food and drug
7 regulation to ensure safety and proper labeling. 21 U.S.C. § 341, et seq. The FDA is charged with
8 developing regulations based on the laws set forth in the FDCA. To preserve “[n]ational
9 uniformity for nonprescription drugs,” Section 379r(a)(2) of the FDCA expressly prohibits any
10 state from establishing “any requirement” that “is different from or in addition to, or that is
11 otherwise not identical with, a requirement under this chapter.” 21 U.S.C. § 379r. A
12 “requirement” includes “any requirement relating to public information or any other form of
13 public communication relating to a warning of any kind for a drug.” *Id.* Consequently, the FDCA
14 preempts state law claims imposing requirements on nonprescription (or OTC) drugs that differ
15 from those imposed by the FDCA. *See Kroessler v. CVS Health Corp.*, 977 F.3d 803, 808 (9th
16 Cir. 2020) (“[P]rivate plaintiffs may bring only actions to enforce violations of state laws
17 imposing requirements identical to those contained in the FDCA.”) (internal citation omitted);
18 *Scheibe v. ProSupps USA, LLC*, 141 F.4th 1094, 1098 (9th Cir. 2025) (“[I]f a product’s label
19 complies with the Act, then the Act preempts any state-law claim that the product is mislabeled.”).

20 Here, the Products’ formulation and labeling have been approved by the FDA, who found
21 the Products to be safe, effective, and equivalent to Mucinex when manufactured pursuant to the
22 ANDAs. Under FDA regulations, these ANDAs had to identify the carbomer used in the Products
23 and include information showing the manufacturing processes for the Products, the specifications
24 for benzene in the carbomer and finished Products, and the language on the label. Plaintiff does
25 not allege that Amneal manufactured the Products in any way that deviated from the ANDAs
26 approved by the FDA. Though the FDA is now changing its requirements regarding benzene, the
27 FDA still permits the use of benzene-containing carbomers until August 2026. RJN, Ex. 6 at 1

n.3. Accordingly, because the Products were found by the FDA to comply with the FDCA, then allegations that the products were “adulterated,” “misbranded,” or “not equivalent to brand name Mucinex,” and “illegal to sell” under California state law are preempted. *See Daugherty v. Padagis US LLC*, No. 24-CV-02066-EMC, 2025 WL 2243622, at *7 (N.D. Cal. Aug. 6, 2025) (collecting cases holding that “§ 379r(a) preempts consumer claims seeking to mandate under state law disclosure of benzene or its risks”); *Howard v. Alchemee, LLC*, No. 2:24-CV-01834-SB-BFM, 2024 WL 4272931, at *9 (C.D. Cal. Sept. 19, 2024) (finding plaintiffs’ claim that defendants sold “an inherently adulterated product—amounting to a criminal act—” preempted because it was “inconsistent with the FDA’s approval of” the ingredient at issue).

Plaintiff’s arguments to the contrary are unpersuasive. First, Plaintiff argues that preemption is an affirmative defense inappropriate for a motion to dismiss; but courts often address preemption at the motion to dismiss stage. *See, e.g., Sidhu v. Bayer Healthcare Pharms. Inc.*, No. 22-CV-01603-BLF, 2022 WL 17170159, at *6 (N.D. Cal. Nov. 22, 2022); *Puri v. Costco Wholesale Corp.*, No. 5:21-CV-01202- EJD, 2021 WL 6000078, at *5 (N.D. Cal. Dec. 20, 2021)/

Second, Plaintiff cites to a provision in Section 379r(e) that states “[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.” 21 U.S.C. § 379r(e). However, Plaintiff does not allege violations of California’s product liability laws. Plaintiff only seeks relief for economic loss, and California bars product liability claims based on pure economic loss as a matter of law. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 790 (2002) (explaining that “if the damage consists solely of economic losses, recovery on a products liability theory is unavailable”).

Third, Plaintiff argues that mere FDA approval is not a panacea for all claims related to the Products. This is true; products approved by the FDA can still be misbranded, adulterated, and illegal to sell if they deviate from the specifications approved by the FDA or if the allegations concern matters not approved by the FDA. *See, e.g., Henning v. Luxury Brand Partners, LLC*, No. 22-CV-07011-TLT, 2023 WL 3555998, at *6 (N.D. Cal. May 11, 2023). However, the Products here were approved by the FDA to contain the carbomer manufactured using benzene

and to label the Product as they currently exist. To the extent Plaintiff claims that Amneal should have formulated the Products using a different carbomer or included additional language on the label, those claims are expressly preempted, as they would impose an obligation on Amneal that is “different from” a requirement under the FDCA. The Court also finds Plaintiff’s reliance on *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 814 (N.D. Cal. 2019), unavailing. The court there found that state law claims were not preempted even when the drugs were FDA-approved because the defendant “could have complied with both state and federal law by formulating a drug” with fewer side effects for FDA approval; but that case concerned the *impossibility* *preemption* doctrine, and the drug at issue was a *prescription* drug for which express preemption is unavailable. *See id.*

Finally, Plaintiff argues that her UCL claim, which is based on a violation of the California Sherman Law, cannot be preempted because the Sherman Law incorporates all FDCA requirements. The Ninth Circuit recently held that certain Sherman Law claims are not *categorically* preempted because the California law incorporates all FDCA requirements. *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 848 (9th Cir. 2024), *cert. denied*, 145 S. Ct. 1922, 221 L. Ed. 2d 663 (2025) (“Because the Sherman Law incorporates all the federal food labeling requirements, it is ‘identical’ to federal standards and not expressly preempted. It is expressly permitted.”); *see also Navarro v. Walgreens Boots All., Inc.*, No. 1:24-CV-00290-JLT-SAB, 2025 WL 1411406, at *14 (E.D. Cal. May 15, 2025) (“[T]o the extent Plaintiffs’ state law claims are parallel claims brought for violations of cGMPs, those claims are not categorically preempted.”). However, in *Sprouts* and the district court cases Plaintiff cites, the FDA had not explicitly found the contents and labels challenged by the plaintiffs to be in compliance with the FDCA. Whereas here, challenging the FDA-approved content and label as adulterated and deceptive under California law—even California law that incorporates the FDCA—is still an attempt by Plaintiff to impose a requirement that is different from or in addition to the federal requirement.⁵ *See*

⁵ Likewise, Plaintiff’s attempts to frame her claims as separately challenging “manufacturing practices” and “omissions” also do not change this dispositive fact.

Kanter, 99 Cal. App. 4th at 795 (“[W]hen a state law claim, however couched, would effectively require a manufacturer to include additional or different information on a federally approved label, it is preempted.”).

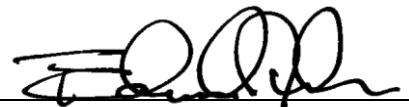
Therefore, the Court finds Plaintiff’s claims expressly preempted under Section 379r(e). The Court need not examine Defendants’ remaining arguments.

IV. CONCLUSION

Based on the foregoing, the Court **GRANTS** Defendants’ motion to dismiss with leave to amend. *Lopez*, 203 F.3d at 1127 (“[C]ourt should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts.”). Should Plaintiff wish to amend her complaint, she must file the amended complaint by **October 20, 2025**.

IT IS SO ORDERED.

Dated: September 29, 2025



EDWARD J. DAVILA
United States District Judge